## UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE: COLUMBIA UNIVERSITY ) MDL NO. 1592
PATENT LITIGATION )

## MEMORANDUM AND ORDER

WOLF, D.J. August 18, 2004

For the reasons described more fully in court on August 16, 2004, the court is allowing the plaintiffs' Motion for Limited Discovery Relevant to the Issue of Non-Statutory Double Patenting (the "Motion"). With the agreement of the plaintiffs, which are drug companies, the court is entering a protective order concerning the information produced as a result of the Motion being allowed.

The Motion seeks discovery of the prosecution history of a pending patent application, Application No. 08/477,159 (the "'159 application"). The defendant in these case, the Trustees of Columbia University in the City of New York ("Columbia") opposes the Motion. Normally, a pending patent application and its prosecution history are confidential. See 35 U.S.C. §122.

¹Despite the requirement of confidentiality imposed by 35 U.S.C. §122, the United States Patent and Trademark Office has, on multiple occasions, inadvertently released to third parties, including the plaintiffs and their attorneys, confidential portions of the '159 application prosecution history in response to requests for the application as filed, to which the public is entitled because it is referenced by the patent-in-suit, U.S. Patent No. 6,455,275 (the "'275 patent"). The protective order the court is entering restricts disclosure of the entire prosecution history of the '159 application regardless of how the plaintiffs and their attorneys obtained it. The court has expressed serious doubts as to whether it would ordinarily be permissible or appropriate to

Therefore, in deciding the Motion, the court has used the balancing test adopted by many other district courts as articulated in <a href="#Fischer Imaging Corp. v. Lorad Corp.">Fischer Imaging Corp. v. Lorad Corp.</a>, 148 F.R.D. 273 (D. Colo. 1993).

Information contained in a patent application may have some relevance in a patent infringement action [or declaratory judgment action], and, thus, a request for such information may meet the liberal standard of relevancy under Fed. R. Civ. P. 26. However, it is also well established that materials relating to a patent application are confidential, and, therefore, enjoy a degree of protection against disclosure. For example, 35 U.S.C. §122 expressly provides that patent applications confidential unless disclosure shall be kept authorized by the applicant. This statutory prohibition is not binding on the courts. Paper Converting Machine Co. v. Magna-Graphics Corp., 207 U.S.P.Q. 1136 (E.D. Wisc. 1980); Ideal Toy Corp. v. Tyco Industries, Inc., 478 F. Supp. 1191, 1192 (D. Del.1979). Nevertheless, the courts have uniformly recognized that a heightened relevancy standard must be applied to patent applications and materials related thereto.

Generally, the courts have employed a balancing test in determining whether or not to permit discovery of a patent application, weighing the requesting party's

restrict distribution of information obtained independently of discovery in this case in view of the heavy presumption against prior restraints on speech. <u>See</u> June 23, 2004 Order (Docket No. 33) (questioning reasoning of <u>Public Citizen Health Research Group</u> v. FDA, 953 F. Supp. 400, 404-05 (D.D.C. 1996) (rejecting First Amendment arguments) in view of <u>Seattle Times Co. v. Rhinehart</u>, 467 22, 26, 32, 33-34 (1984) (distinguishing between U.S. 20, information obtained only through discovery and information obtained independently)). However, at the August 16, 2004 hearing, in an effort to persuade the court to allow the Motion, the plaintiffs and their attorneys offered to waive any First Amendment right they may have to discuss information they obtained independently of this litigation and, instead, to subject that information to the protective order proposed for any parts of the '159 prosecution history obtained in discovery. Therefore, the court did not need to resolve the First Amendment issue.

interest in the materials against the objector's legitimate interest in the secrecy. Davco Manufacturing Corp. v. Peninsular Diesel, Inc., 128 F.R.D. 91, 93 (N.D. Ohio 1989); Ideal Toy Corp. v. Tyco Industries, Inc., 478 F. Supp. at 1192 & 93; <u>Cleo Wrap Corp. v. Elsner</u> Engineering Works, Inc., 59 F.R.D. 386, 388 (M.D. Pa. 1972). A demonstration of direct relevancy will tip the scale in favor of disclosure. Paper Converting Machine Co. v. Magna-Graphics Corp., 207 U.S.P.Q. 1136 (E.D. Wis. 1980). On the other hand, the fact that the parties are competitors is a matter which weighs against disclosure. Wolowitz v. United States, 185 U.S.P.Q. 155 (Ct. Cl. 1975); Struthers Scientific & Int'l Corp. v. General <u>Foods Corp.</u>, 45 F.R.D. 375, 381 (S.D. Tex. 1968). can obtain sufficient Likewise, if the plaintiff information regarding the allegedly infringing product from other sources, discovery of the defendant's patent application generally will be denied. Ideal Toy Corp. v. Tyco Industries, Inc., 478 F. Supp. at 1193; Wolowitz v. United States, 185 U.S.P.Q. 155 (Ct. Cl.1975); Cleo Wrap Corp. v. Elsner Engineering Works, Inc., 59 F.R.D. at 388.

## Id. at 274.

As indicated earlier, the '159 application as filed is publicly available because it is listed as a publication in the patent-in-suit, the '275 patent. The Motion seeks discovery of only the '159 application's prosecution history. Since the '159 application is part of the same family of patents as the '275 patent and contains some identical claim language, statements that Columbia has made and will make during the prosecution of the '159 application are directly relevant to the claim construction of the '275 patent. See Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1350 (Fed. Cir. 2004); Laitram Corp. v. Morehouse Indus., Inc., 143 F.3d 1456, 1460 n.2 (Fed. Cir. 1998).

The harm to Columbia that will result from disclosure is not

sufficient in the facts and circumstances of these cases to outweigh the showing of direct relevance that the plaintiffs have made. Columbia does not use the '275 patent or any other patent involved in this case for commercial purposes. Rather, it has historically licensed the patents to plaintiffs and other drug companies. Therefore, Columbia and the plaintiffs are not competitors.

Since the '159 application as filed is publicly available and the written description has been publicly available since 1983, the plaintiffs will not learn about an invention that is not yet the subject of an issued patent. Thus, a primary reason for maintaining the confidentiality of patent prosecution does not exist in this case. See, e.g., Lee Pharms. v. Kreps, 577 F.2d 610, 616 (9th Cir. 1978). Although the plaintiffs will learn about the scope of the claims of any patent that issues from the '159 application earlier than the general public, the protective order being issued will prevent the plaintiffs from using that information to begin designing around any of Columbia's claims before the '159 application issues as a patent. It will also generally prevent the public from receiving the prosecution history as, unlike the plaintiffs, the public lacks a particularized need that outweighs Columbia's interest in keeping the prosecution history confidential.<sup>2</sup>

In addition, the disclosure of the prosecution history of the '159 patent should facilitate the full, fair, and efficient preparation of the parties' motions for summary judgment and, if necessary, trial concerning the plaintiffs' contention that the '275 patent is invalid under the doctrine of non-statutory double patenting. In June 2004, the court identified this as an issue that could be prepared for presentation and resolution promptly, either on cross-motions for summary judgment or at a trial to be conducted in December, 2004. See June 23, 2004 Order (Docket No. 32). Resolution of this issue may, as a practical matter, end this litigation, which otherwise promises to be complex and protracted, and necessarily create uncertainty about plaintiffs' rights to produce drugs that are important to human health. Thus, it is particularly in the interests of justice in this Multidistrict Litigation that plaintiffs receive promptly any information that is directly relevant to the non-statutory double patenting issue,

The court recognizes that parts of the '159 prosecution history may become public if the court relies on it in deciding the foreseeable motions for summary judgment or if they are made part of the public record at any trial. See FTC v. Std. Fin. Mgmt. Corp., 830 F.2d 404 (1st Cir. 1987); Anderson v. Cryovac, Inc., 805 F.2d 1 (1st Cir. 1986) (discussing public right of access to materials on which a court relies in determining the substantive rights of litigants); Std. & Poor's Corp. v. Commodity Exchange, Inc., 541 F. Supp. 1273 (S.D.N.Y. 1982) (discussing public right of access to civil trial and court's authority to close portions of trial to protect trade secrets). This does not, however, alter the outcome of the balancing analysis.

including any such information that may be included in the prosecution history of the '159 application.

Accordingly, it is hereby ORDERED that:

- 1. The Motion (Docket No. 60) is ALLOWED.
- 2. The June 23, 2004 Protective Order, which was entered with the agreement of the plaintiffs, is VACATED.
- 3. Columbia shall, by August 20, 2004, produce to the plaintiffs the entire prosecution history of the '159 application.
- 4. Columbia shall, within five days of any addition to the prosecution history of the '159 application, supplement the production ordered in paragraph 3.
- 5. With the agreement of the plaintiffs and their attorneys, the documents, records, and information they contain that the plaintiffs receive pursuant to paragraphs 3 and 4 of this Order, as well as the prosecution history of the '159 application received from any other source, shall only be disclosed to plaintiffs' inside and outside counsel and the individuals necessary to assist them in this case, including but not limited to testifying and non-testifying experts, litigation support vendors, and support staff. Each of the foregoing will be deemed an "Authorized Individual" for the purposes of this Order.
- 6. The documents, records, and information they contain shall be used by each Authorized Individual solely for the purpose of litigating matters in this case.

- 7. Each Authorized Individual shall not divulge the documents, records, and information they contain to anyone who is not an Authorized Individual.
- 8. Submissions to the court referring to documents, records or information that is subject to this Order shall be filed under seal with redacted versions to be made part of the public record.
- 9. Each Authorized Individual except for secretarial-type support staff shall promptly file a statement under oath representing that he or she has read this Order, recognizes that he or she is subject to it, and that any violation of it may be deemed a civil and/or criminal contempt.
- 10. Any violation of this Order may be deemed a civil and/or criminal contempt.

/s/ Mark L. Wolf
UNITED STATES DISTRICT JUDGE